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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,928	11/26/2003	Bonnie B. Sandel	102289-100	1181

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WIGGIN AND DANA LLP
ATTENTION: PATENT DOCKETING
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EXAMINER	
FRAZIER, BARBARA S	
ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,928	SANDEL ET AL.	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *7 and 16-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-15 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/2/08*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-33 are pending in this application. Addition of new claim 33 is acknowledged.

2. Claims 17-32 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 11/1/07.

3. Claims 7 and 16 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/1/07.

4. Claims 1-6, 8-15, and 33 are examined.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-6, 8-15, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laver (US Patent 5,516,472), Dawson-Andoh et al. (Abstract from Vinyltec 2003 Conference), and Lyon et al (US Patent 6,042,877).

The claimed invention is drawn to a process for incorporating a metal salt of an antimicrobial onto an outer surface of, or into a porous inner portion of, an extruded or

molded plastic product which comprises the steps of providing a metal-containing extruded or molded product, and contacting said product with an aqueous solution of water-soluble biocide to form an antimicrobially protected product having a water-insoluble metal salt of a biocide on the surface, and/or in the porous inner portion, thereof, according to the limitations of claim 1 (see claim 1).

Laver teaches an extruded synthetic wood composition, including a process for the production of a composite material comprising the steps of combining cellulosic material with a sufficient amount of thermoplastic material to form a combined product, and extruding the combined product under sufficient conditions to blend the combined product together into a homogenous mixture (see col. 2, lines 47-52). The composite also contains a lubricant such as zinc stearate (col. 7, lines 18 – 22). This is consistent with Applicant's specification, which teaches that the metal is sometimes incorporated "by means of a functional additive, such as a lubricant" (page 12, lines 19-20), and "These metals are typically present… as stearates… illustrative salts include zinc stearate" (page 13, lines 1-8). The thermoplastic material may be polyethylene (col. 6, lines 48 – 52); polyethylene and zinc stearate are contained in the preferred formulation (col. 7, line 60 – col. 8, line 7). The product is extruded at a temperature between about 100 and 400F (col. 3, lines 20-22); since Applicants have not defined their term "elevated temperature" in the specification, examples, or claims, the term is interpreted to include temperatures between 100 and 400F.

Laver does not teach the step of contacting the extruded product with a water-soluble biocide. However, one skilled in the art would recognize the need to apply a

biocidal agent to the product of Laver. As evidence, Dawson-Andoh et al teach that PVC-wood flour composite materials become colonized and discolored upon exposure to fungi (see abstract). Since Laver teaches that PVC is a functional equivalent of polyethylene (see col. 6, lines 48-52), one skilled in the art would recognize the need for a biocide to be applied to a polyethylene composite material.

Lyon et al teach a method for the manufacture of anti-microbial articles comprising rinsing a metal-containing substrate with a potentiator, i.e., an anti-microbial agent (biocide) capable of bonding to the metal ion (col. 4, lines 56-59). For the substrate, Lyon et al. teach that "many types of substrates are suitable for use in this invention…substrates are those considered useful in applications where anti-microbial activity is advantageous" (col. 5, lines 37-40). Also, the substrates may comprise any of a variety of natural or synthetic materials; a particularly useful substrate shape is a fiber made of natural and/or synthetic materials, said natural fibers including pulp fibers (col. 5, lines 55-60). Additionally, the substrate may include thermoplastics such as polyethylene (col. 7, lines 32-33). Suitable potentiators include pyrithiones (col. 5, lines 6-7), and sodium pyrithione is preferred (col. 7, lines 27-30 and Preparative Procedure B, column 8).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to contact the metal-containing substrate of Laver with an antimicrobial agent according to the process of Lyon et al; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because of the need to protect composite materials from microbial attack is already known, as

evidenced by Dawson-Andoh et al, and because contacting the metal-containing substrate with an antimicrobial agent according to the process of Lyon et al provides the benefits of making a durable, long-lasting anti-microbial article which does not require regeneration or further processing of the final article, as taught by Lyon et al (see col. 1, lines 49-51). One skilled in the art would reasonably expect success from applying the antimicrobial as taught by Lyon et al to the product taught by Laver because both references are drawn to metal-containing substrates which may contain thermoplastics and natural fibers.

Regarding claims 2 and 3, Lyon et al teach that suitable potentiators include pyrithiones (col. 5, lines 6-7), and sodium pyrithione is preferred (col. 7, lines 27-30 and Preparative Procedure B, column 8).

Regarding claims 4 and 5, Laver teaches that the composite contains a lubricant such as zinc stearate (col. 7, lines 18 – 22).

Regarding the amount of metal present on the surface of the extruded product (claims 6 and 8), it is noted that Laver is silent with respect to the amount of metal present on the surface of the extruded product. However, the amount of zinc stearate used to make the product of Laver is 3 parts (per 153 parts total; see col. 7, line 66), or approximately 2%, and the claimed invention uses 2.5% zinc stearate (see Example 1, page 17, line 19 of the specification). Therefore, it appears that the amount of zinc in Laver would produce a product having an amount of metal present on the surface, or in the porous interior portion, within the ranges claimed in claims 6 and 8, and/or one skilled in the art would be motivated to manipulate the amount of zinc by routine

experimentation in order to optimize the resultant amount of water-insoluble biocide formed on the surface or in the porous interior portion.

Regarding the water solubility of the water-insoluble metal biocide (claims 9 –11), it is noted that the property of water solubility is inherent within the compound itself; therefore, the water solubility of the zinc pyrithione of Lyon et al. would necessarily have the same water solubility of the zinc pyrithione of the claimed invention.

Regarding the surface concentration of the water-insoluble metal biocide (claim 12), it is noted that Lyon et al. is silent with respect to the surface concentration of zinc pyrithione. However, the claimed invention uses 0.2 – 2% sodium pyrithione (Example 1, pages 17 and 18 of the specification), and Lyon et al. uses a sodium pyrithione solution adjusted to a pyrithione concentration of 3000 ppm (Preparative Procedure B, column 8), or 0.3%. It appears that the amount of sodium pyrithione in Lyon et al. would produce a product having a surface concentration within the range claimed in claim 12, and/or one skilled in the art would be would be motivated to manipulate the amount of zinc by routine experimentation in order to optimize the resultant amount of water-insoluble biocide formed on the surface or in the porous interior portion.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes limitations that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph). As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. *In re Brown,* 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Regarding the plastic-forming composition (claims 13-15), Laver teaches that the virgin thermoplastic materials may be polyethylene or low density polyethylene (col. 6, lines 48 – 52), or recyclables (see abstract), and cellulosic materials such as wood chips, wood fibers, and wood flour may be used (col. 6, lines 31-36).

Regarding claim 33, Lyon et al teach that, to maximize the anti-microbial activity of the article, the entire available surface of the substrate is preferably exposed to the potentiator (i.e., antimicrobial) solution (col. 5, lines 1-4). An example of this is soaking the substrate in the pyrithione anti-microbial solution for one hour (col. 8, lines 35-37). One skilled in the art would reasonably interpret "entire available surface", contacted by soaking, to include the porous interior portion of the substrate.

Response to Arguments

7. Applicant's arguments filed 5/20/08 have been fully considered but they are not persuasive.

Applicants first argue that the mere disclosure of polyethylene and pulp fibers among a wish list of substrates suitable for the method disclosed by Lyon et al does not motivate or lead a person skilled in the art to select that material from Lyon's list and apply the method to a cellulose-polyethylene composite produced by the Laver process.

This argument is not persuasive because Lyon et al still clearly teach that metal-containing substrates derived from polyethylene and pulp fibers are suitable substrates for the forming the antimicrobial product. There is no evidence of record that the individual components would no longer be suitable substrates once they are formed

together in a composite material. Therefore, since natural fibers and thermoplastics are suitable substrates for forming the antimicrobial product, a composite material of natural fibers and thermoplastics would also be a suitable substrate for forming the antimicrobial product, absent evidence to the contrary.

Applicants also argue that there is no proper motivation to apply only step (2) of the process of Lyon et al, because Lyon et al teach the utilization of the chelating polymer-metal ion-potentiator complex as an active biocide to provide sustaining antimicrobial effect to the treated substrate.

This argument is not persuasive. Nowhere does Lyon et al state that a "chelating polymer-metal ion-potentiator complex" is formed, much less that it is this particular "complex" which confers antimicrobial activity to the product. On the contrary, Lyon et al only refer to the bond between the potentiator, i.e., and anti-microbial agent capable of bonding to the metal ion, and the ion itself (see col. 4, lines 56-59). The potentiator is chosen with regards to the chelating polymer only to the extent that the potentiator does not dissociate the metal ion from the polymer (in which case, the metal ion would no longer be a part of the substrate), **not** because the potentiator forms a complex with the polymer.

Applicants also argue that there is no motivation to apply only step (2) of a two-step process disclosed by Lyon et al to a composite disclosed by Laver.

This argument is not persuasive. The teachings of Lyon et al are relied upon to show that it is known to apply an antimicrobial solution to a metal-containing substrate, wherein a bond forms between the antimicrobial agent and the metal ion of the

substrate. As stated above, the bond is between the metal ion itself and the antimicrobial agent; therefore, it would be prima facie obvious to one skilled in the art to be able to apply the step of contacting the antimicrobial solution with a metal-containing substrate, such as the substrate of Laver, with a reasonable expectation of success.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

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